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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,789	11/12/2003	Hallett H. Mathews	4002-3449/PC466.02	7185
52196	7590	11/30/2005		
KRIEG DEVAULT LLP ONE INDIANA SQUARE, SUITE 2800 INDIANAPOLIS, IN 46204-2709			EXAMINER BLANCO, JAVIER G	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 11/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/706,789	Applicant(s) MATHEWS, HALLETT H.	
	Examiner Javier G. Blanco	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-43, 48-56 and 86-92 is/are pending in the application.
- 4a) Of the above claim(s) 39-43 and 52-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37, 38, 48-51, 56, and 86-92 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's amendment of claim 37 in the reply filed on September 12, 2005 is acknowledged.
2. Applicant's cancellation of claims 57-85 in the reply filed on September 12, 2005 is acknowledged.
3. Applicant's addition of claims 86-92 in the reply filed on September 12, 2005 is acknowledged.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 37, 38, 48-51, 56, and 87 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

- a. Regarding independent claim 37 (and dependent claim 87), newly added limitation "*having a vertebral endplate contacting area no greater than 0.5 square inches*" (see claim 55 and claim 62, at line 5 respectively) was not disclosed or suggested in the specification (or parent case

Art Unit: 3738

09/918,332). The specification only talk about ranges, and those ranges are referred to as “about”. Claims 38, 48-51, and 56 depend on claim 37.

b. Because of the procedure outlined in M.P.E.P. 2163.06 for interpreting the claims, it is noted that other art may be applicable under 35 U.S.C. 102 or 35 U.S.C. 103(a) once the aforementioned problem is corrected.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 37, 38, 48-51, 56, and 86-92 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Felt et al. (US 5,888,220 A; cited in Applicant’s IDS).

Felt et al. disclose a spinal surgical instrument for distracting a disc space comprising: (i) a shaft (e.g., delivery cannula 10) extending between a proximal end and a distal end; and (ii) an inflatable portion (e.g., balloon 12) adjacent said distal end (see Figure 1), said inflatable portion having a reduced size configuration for insertion into the disc space (see column 3, lines 19-21; column 5, lines 54-59) and an enlarged inflated configuration (see column 3, lines 19-21; column 5, lines 54-63), wherein when in said inflated configuration said inflatable portion defines an upper vertebral endplate contacting surface and an opposite lower vertebral endplate contacting surface (see column 5). A biomaterial is delivered in a flowable form through delivery cannula

Art Unit: 3738

10 and said biomaterial is curable after delivery (see column 3 and columns 5-7). Another cannula can be used to deliver biomaterial to the disc space (see column 6, lines 36-53; see entire document). A list of suitable flowable/curable biomaterials is disclosed at columns 7-9.

Felt et al. disclose at column 5, lines 21-29 the desirability of distracting the disc space to any desired final dimensions and position. Furthermore, Felt et al. disclose at column 6, lines 6-20 that the balloons can be provided in any suitable form/shape, depending on the manner in which the biomaterial is to be delivered and cured. Although Felt et al. intended purpose is to *“reconstruct the disc in a manner that more closely approximates the overall physical characteristics and relationship of the original annulus and nucleus”* (see column 6, lines 50-53), they did not particularly disclose the upper and lower vertebral endplate contacting surfaces as each having an area in the range of 0.1 square inches to 0.5 square inches. It should be noted that said area would vary depending on the degree to which the balloon is inflated. Therefore, at any given moment during inflation, the balloon will comprise an upper/lower vertebral endplate contacting area in the range of 0.1 square inches to 0.5 square inches. Also, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the the upper and lower vertebral endplate contacting surfaces as each having an area in the range of 0.1 square inches to 0.5 square inches since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Response to Arguments

8. Applicant's arguments filed September 12, 2005 have been fully considered but they are not persuasive.

a. The Applicant argues that Felt et al. '220 does not disclose "*vertebral endplate contacting area no greater than 0.5 square inches*". The Examiner respectfully disagrees. As indicated above (see 112 1st paragraph rejection), this limitation was not disclosed in the instant application. Also, and as previously indicated, said area would vary depending on the degree to which the balloon is inflated. Therefore, at any given moment during inflation, the balloon will comprise an upper/lower vertebral endplate contacting area in the range of 0.1 square inches to 0.5 square inches (or at least less than 0.5 square inches).

b. The Applicant argues that Felt et al. '220 does not disclose the inflatable portion (i.e., balloon) as including "*a spherical shape*". The Examiner respectfully disagrees. As indicated in the rejection above, Felt et al. disclose at column 5, lines 21-29 the desirability of distracting the disc space to any desired final dimensions and position. Furthermore, Felt et al. disclose at column 6, lines 6-20 that the balloons can be provided in any suitable form/shape, depending on the manner in which the biomaterial is to be delivered and cured. Also, Felt et al. intended purpose is to "*reconstruct the disc in a manner that more closely approximates the overall physical characteristics and relationship of the original annulus and nucleus*" (see column 6, lines 50-53). It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the balloon to have/include a spherical shape, since applicant has not disclosed that such solve any stated problem or is anything more than one of

numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of distracting a disc space. *In re Dailey and Eilers*, 149 USPQ 47 (1966).

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (7:30 a.m.-4:00 p.m.), first Friday of the bi-week off.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications. Any inquiry of a general nature or relating to

Art Unit: 3738

the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB

November 23, 2005

A large, stylized handwritten signature in black ink, consisting of several loops and a long horizontal stroke.A handwritten signature in black ink, appearing to read 'David H. Willse', written in a cursive style.

David H. Willse
Primary Examiner